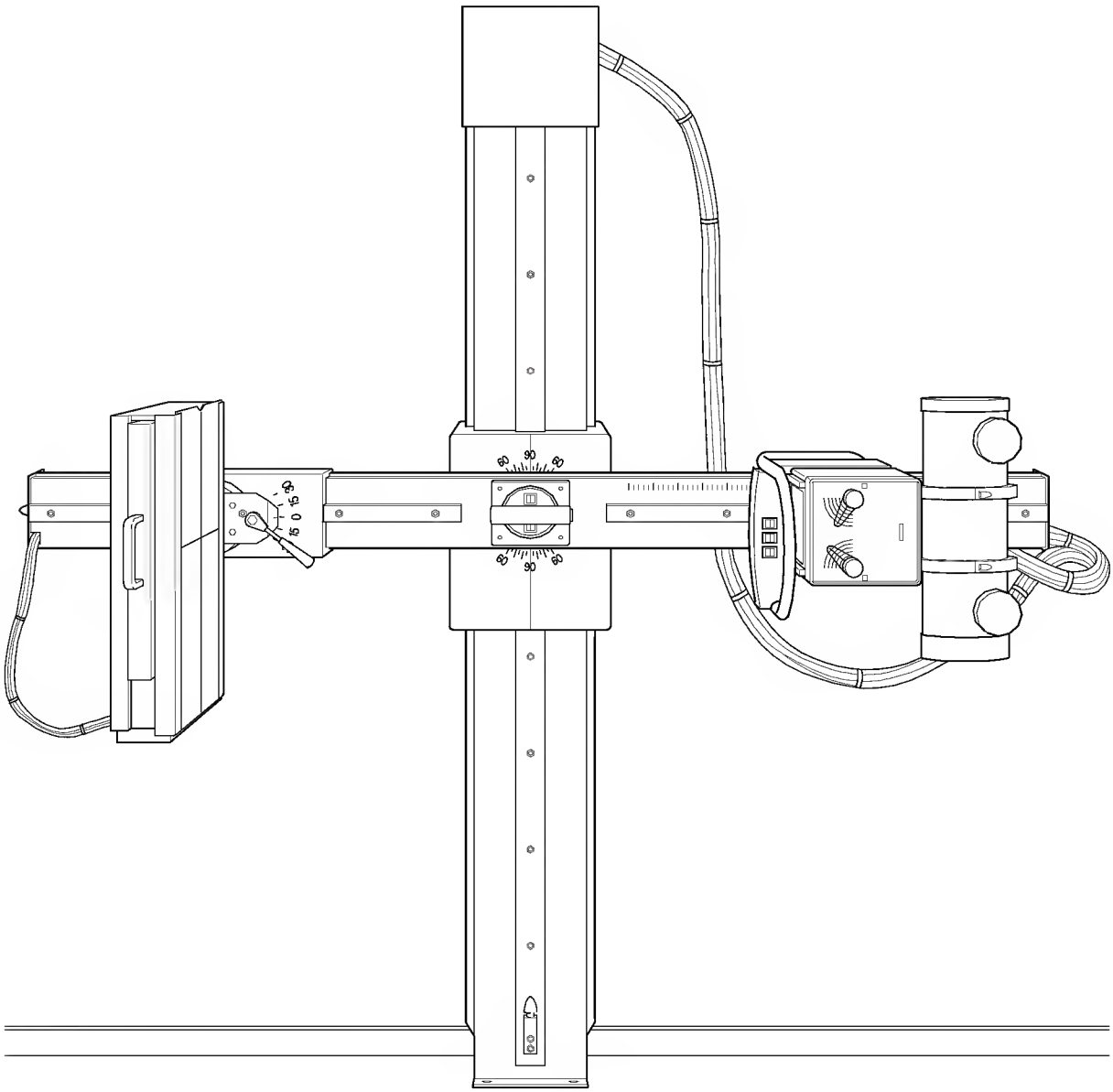
OPERATING INSTRUCTIONS Cosmos-2



CE 0125

English Edition

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Important Note:

To ensure proper operation of this product it is essential that the service personnel is familiar with the **"Operating Instructions"** which should be studied carefully before use.

Special attention is to be given to the chapter "Safety Notes"

The equipment must be used in accordance with the safety procedures described below, and must not be used for purposes other than those for which it was designed. The equipment may only be used by persons having recognised qualification, including adequate training in radiation protection, authorising them to perform the examination or treat ment carried out.

It is the responsibility of the user to ensure that the government regulations are observed in the operating conclitions of the equipment.

Technical safety note:

Regulations

If statutory regulations govern the operation of the above equipment, it is the responsibility of the operator to ob serve them.

For the safety of patients, operators and others, as well the efficient functioning of the equipment it is necessary to have periodic service inspections at 12-month intervals according to the maintenance schedule. Please apply to your service organisation for inspection and maintenance.

Inspections intervals must by all means meet the requirements of the respective legislation or government regulations.

Changes and additions to the product must comply with the relevant legislation as well as with the accepted standards of good manufacturing practice.

As manufacturer of electromedical systems, we assume responsibility for the safety of the equipment only if maintenance, repairs and changes are carried out exclusively by us or third parties expressly authorised by us to do so, and if defective parts relating to the safety of the equipment are replaced by genuine spare parts.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of work . Also the certificate should show the date of repair, the name of the service company and the signature of the technician.

Before operating the equipment, the operator must check all devices concerning the safe and efficient functioning.

If the user of this equipment likes to combine the unit with other units, components or assemblies and this can not be made clear from the technical data, he

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must question us as manufacturer or another expert to make sure that the safety of the patients and operator is given by the planned combination.

Product Safety

Electrical safety

Only trained service personnel are permited to remove covers and panels from the x-ray equipment .

In the Federal Republic of Germany, the electrical installation of rooms used for medical purposes must conform to the provisions of the VDE Standard 0107. In all other countries, the provisions of the applicable local laws and regulations have priority.

Mechanical safety

It is the responsibility of the operator to ensure safety of patient while the unit is in operation by visual check, proper patient positioning, and use of devices that are provided.

Danger of injury

The solid black arrows and dotted lines in the illustration show areas which present potential Danger of Injury to operating personal and patient from the equipment motion.

See next page.

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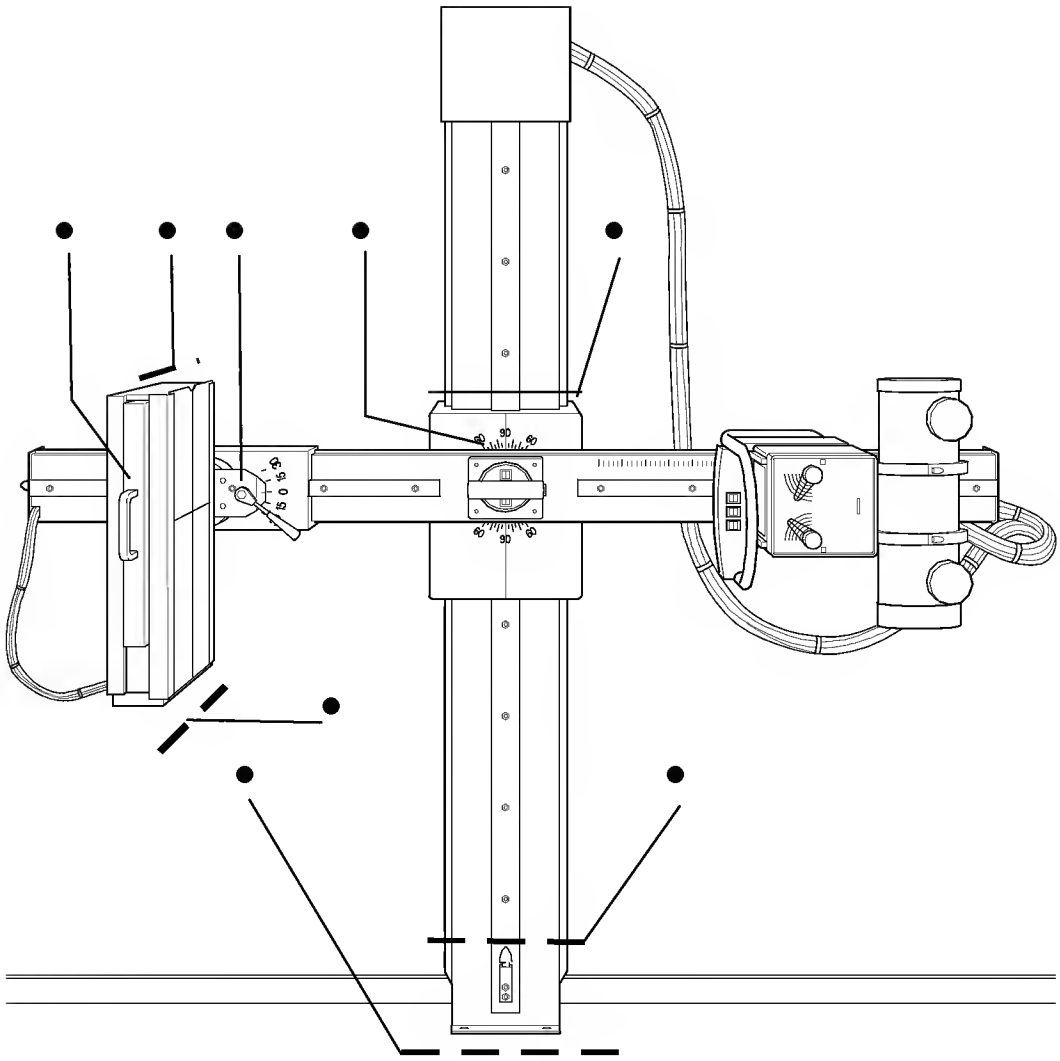

X-Ray Protection.

The unit has no controls with which radiation could be triggered.
Exposure is triggered only from the radiation-protected location of the generator.
The general radiation-protection measures must be observed.

In addition, we recommend the following:

1 Set the tube current as low as possible .
2 Limit the radiation field to the maximum possible extent.
3 Keep as fare away as possible.
4 Provide radiation protection for the patient.

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Explosion Protection

This equipment is not designed for use in areas where explosion hazard can take place.
Only skin cleansing agents may be used which form non-explosive mixtures with air.

Interference Suppression

The equipment complies with the EMC-requirements of the guideline 89/336 EWG. of
* Special board International Electronic Commission (IEC) This unit complies to EN 55011 and the reference value is according EN 55011 Group 1 Class B the international electrotechnical committee (IEC).

Classification of product

The equipment complies to the protection degree of Class 1 and for protection against electric shock Type B.

EC Conformity

The Cosmos-2 to which this declaration relates fulfills the essential requirements for safety of medical electrical equipment and follows the provisions of Medical Device Directive 93/42 EEC part 11 para. 3 according the procedure in annex II.
The CE-Mark is only applicable for the product without X-ray components and Bucky.

The declaration of EC-conformity can be sent to you by request:
Write to:
Hans Pausch
Röntgengerätebau
c/o Quality Assurance Sys. Mgr.
Postfach 28 60
D-91016 Erlangen
Fax #: ..49 9131 99 24 22

Enviroment Condition

Surrounding temperature range	10° C to 40° C
Humidity	20% to 80%
Atmospheric pressure	700 hPa to 1100 hPa

Disposal of equipment

For this equipment there could existlegal disposal regulations. To avoid environmental and personal injury contact your service personnel before shutting down the equipment.

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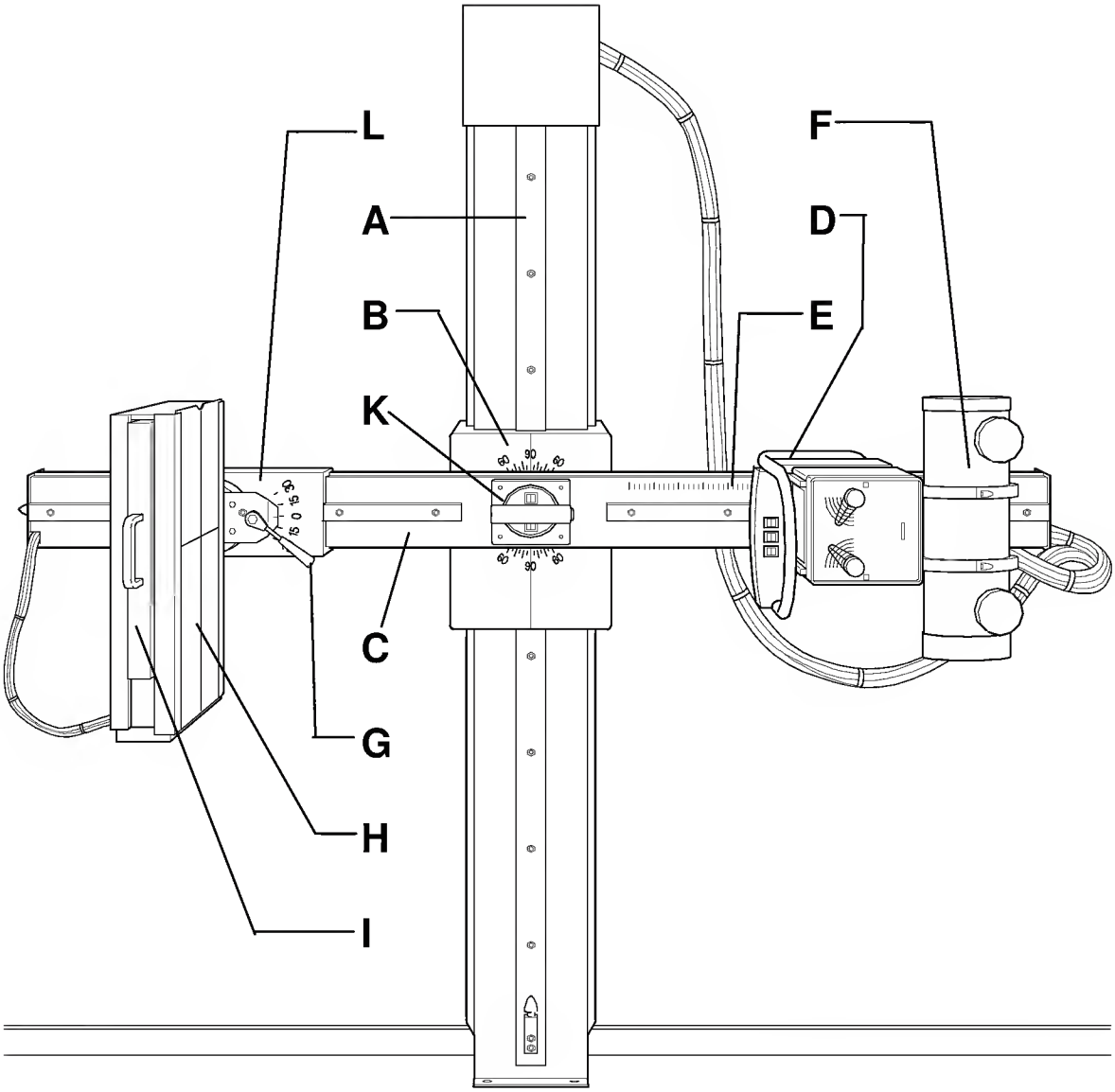
Component Designations



A Column
B Vertical Carriage
C Swivel Arm
D Controls
E SID Scale
F X-Ray Tube with Collimator
G Brake for Bucky Tilt
H Bucky
I Cassette Tray
K Central Control Unit
L Scale for Bucky Angulation

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General

Description

The COSMOS-2 examination unit is universally usable for taking exposures of standing, sitting or recumbent patients.

The X-Ray tube is fixed in centerline to the center of the Bucky.

The Source-Image Distance (SID) is motorized adjustable in a range from 1 m to 2 m .

The Bucky - and X-Ray tube carriage run on ball bearings over the guide rails of the swivel arm.

The Swivel Arm is bearing revolving mounted and can be fixed in any position.

The Rotational Movements are locked electromagnetically.

The Vertical Carriage is guided on ball bearings in its vertical direction of the column and locked in place electromagnetically.

The Bucky unit can be turned 45 degrees and a mechanical detent is provided at zero degrees position.

The Patient table is an independent unit, easily moveable on castors. The twin castors can be locked.

Description

The COSMOS-2 X-Ray unit is a universal work station for doctors practices as well as for hospitals with high-quality exposures. Especially the large vertical movement and the simple rotation together with the easy operation makes the COSMOS-2 patient- and operating friendly.

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Installation Requirements

Floor Space

The system is designed for stationary operation. The approx. floor space required measures 240 x 130 cm; with patient table 340 x 220 cm.

Roomheight

The required roomheight should be 285 cm to work without problems.

Power

The system is equipped for single phase alternating current with fixed installation. The system corresponds to nominal ratings as follow:

Nominal Voltage: 115 / 230 V

Nominal Current: 2 / 1 A

Rated Frequency: 50 / 60 Hz

Nominal Capacity: 230 VA

Mains

The mains connection requires a 30 mA circuit breaker to be installed by the customer. The electrical installation must meet the relevant legislation, e.g. VDE 0107, IEC/SC 62A.

AL-equivalent

The weakening equivalent of the table top (patient pos. table top) is 0,6 mm.
The weakening equivalent of the Bucky - Front plate 0,55 mm.

According to:

DIN EN 60601-1-3 with 100 kV and HWS 3,7 mm AL
and FDA 21 CFR § 1020.30 (n) with 100 kV and HWS 2,7 mm AL.

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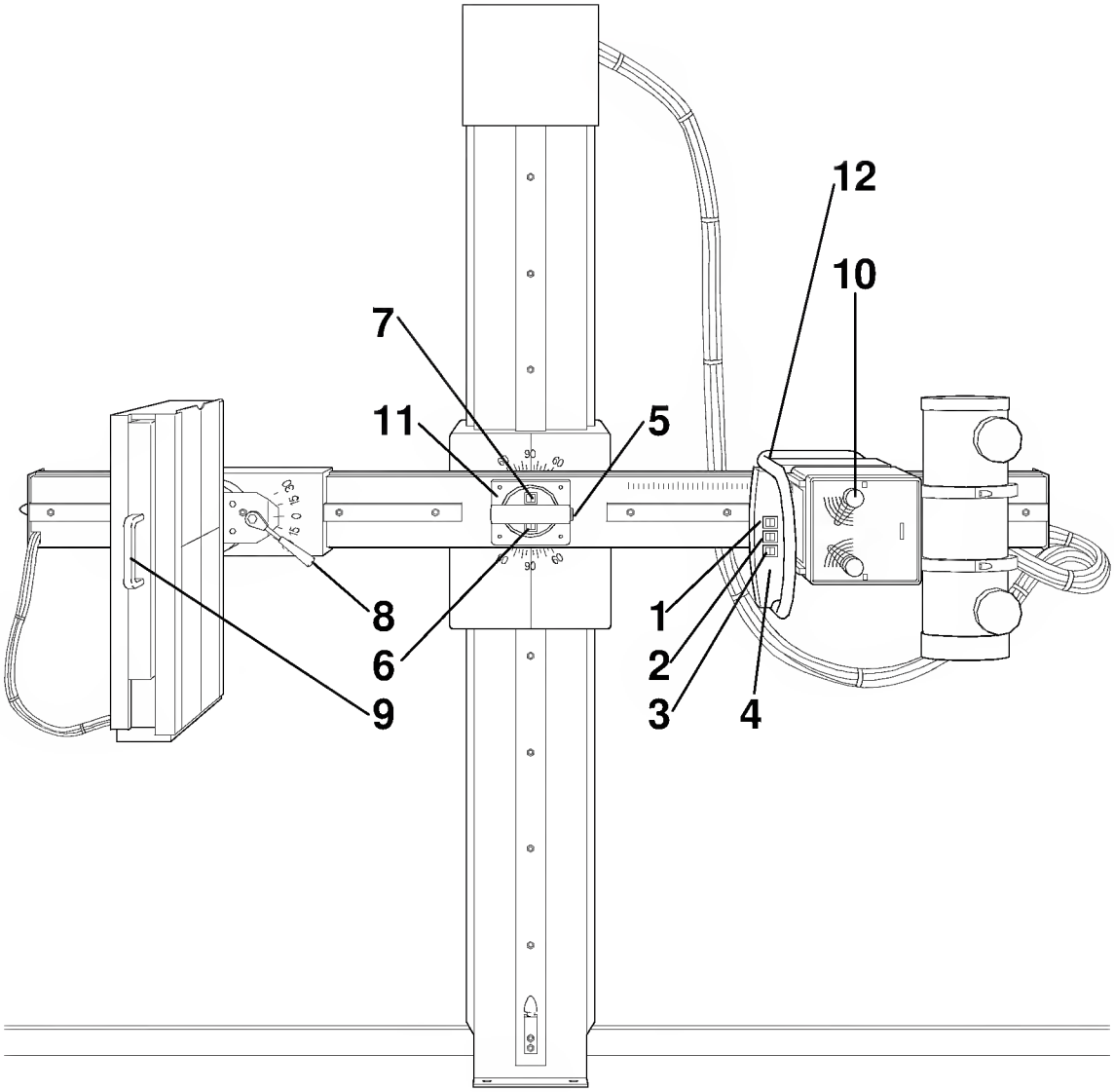
Operating Controls

Arrangement



1 Momentary switch for swivel arm rotation
2 Switch for SID adjustment
3 Switch for vertical movement
4 Indicator light *
5 Switch for vertical movement
6 Switch for SID adjustment
7 Momentary switch for swivel arm rotation
8 Brake lever for Bucky tilt
9 Cassette tray handle
10 Operating controls for Collimator (ref. to manufacturers inst.)
11 Main control handle
12 Control arm

□□ on request

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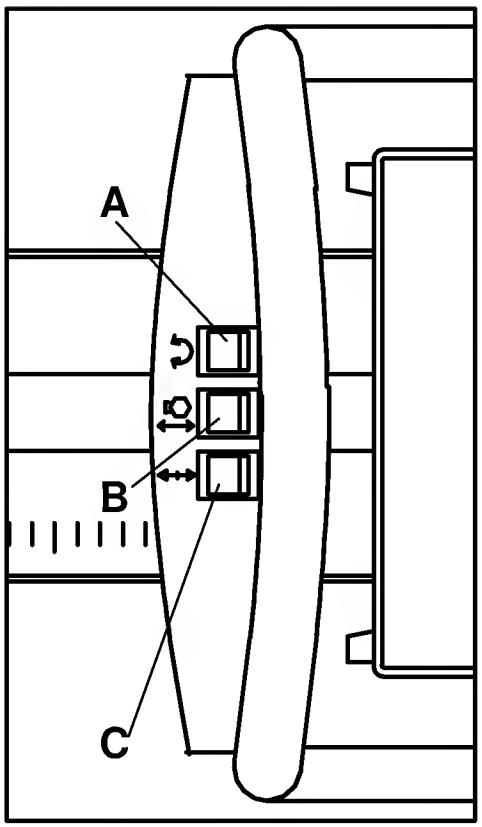
Meaning of Symbols /Function

Momentary switch **A** or **E**

to unlock the rotational brake.
Press the momentary switch **A** or **E**, move the swivel arm in desired working position. Release the switch and the swivel arm will be locked in place.



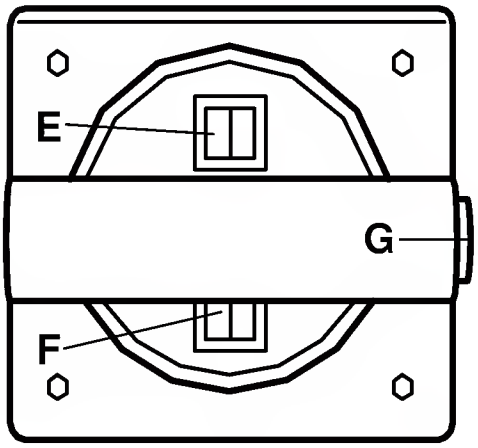
Momentary switch **B** or **F**

for motorized adjustment of the SID.
Press the momentary switch **B** or **F** to increase or decrease the SID. The motor will stop automatically in its end position or when the switch is released in desired position.

Switch **C**

to release the vertical lock.
Press switch **C**. Make required height adjustment and put the switch in off position.

Note: The switch will light up when put into "vertical brake off" position.

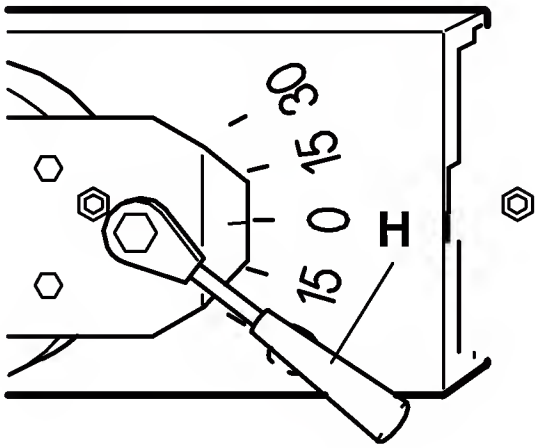


Momentary switch **G**

to release the vertical lock.
Press the momentary switch **G**, move the swivel arm in desired working position. Release the switch and the swivel arm will be locked in place.

Brake lever **H**

to release the Bucky lock.
Loosen brake lever **H** in c.c.w. direction. The Bucky can now be SA □ 30 degrees. Turn brake lever in c.w. direction to lock Bucky in desired position.



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Operation

The unit is ready for operation when switched on.

Emergency-off

Provided an emergency switch has been installed in the examination room, the red switch button must be pushed immediately in case of danger for patients, operating personnel, or equipment. Only after positive elimination of the danger, turn the red emergency off switch clockwise to resume operation.

General

Upon voltage loss, the vertical movement of the unit is released.

Important note

The safety brake will be effected immediately in case that it will be driven to hard against the end limit stops from the top and from below of the column.

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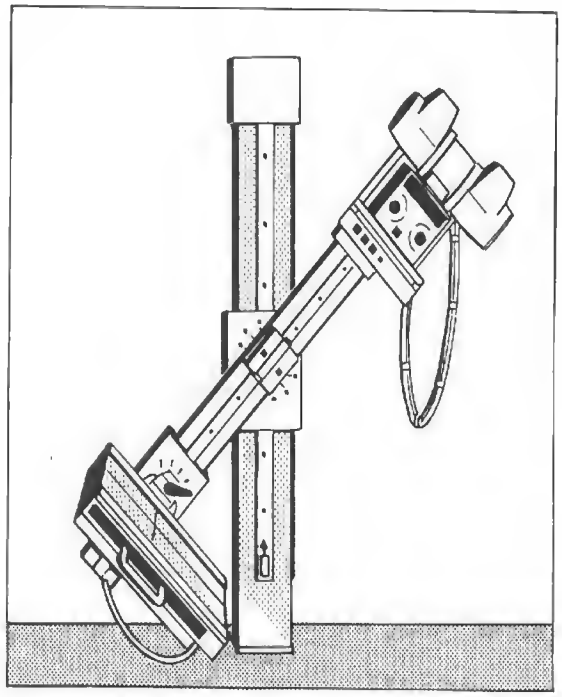
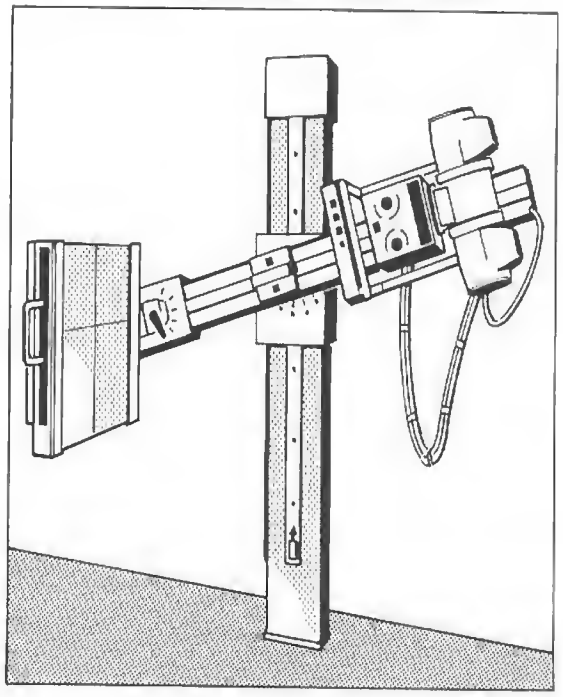
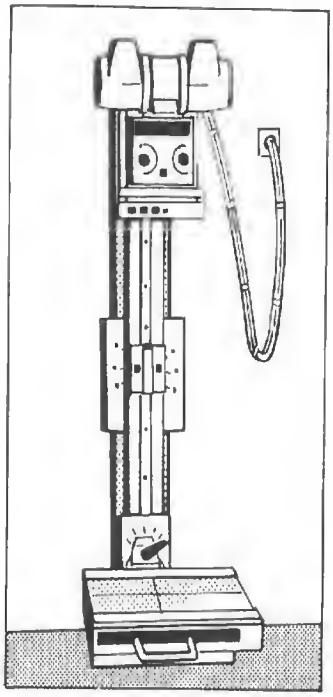
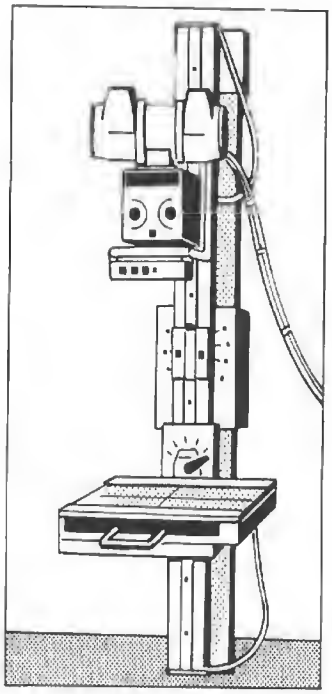
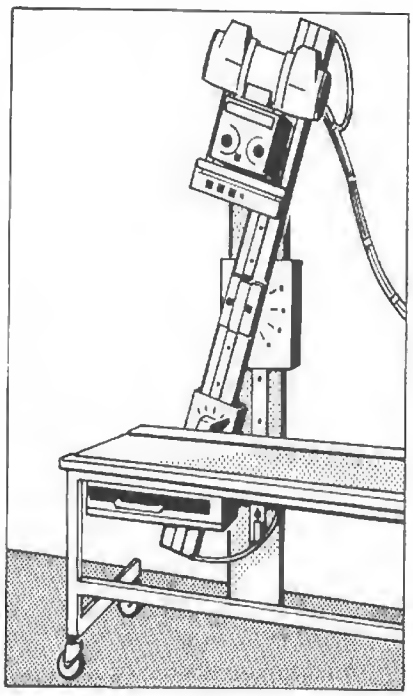
Application examples











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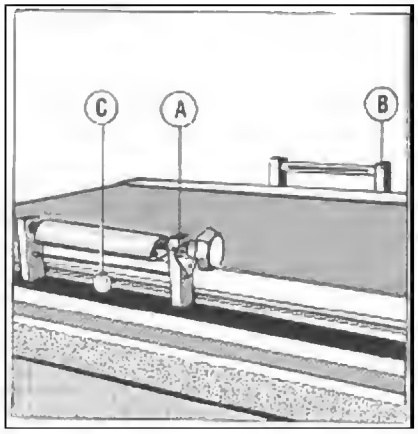
Accessories

Compression Belt / Head Supports / Hip Clamps / Table Mattress

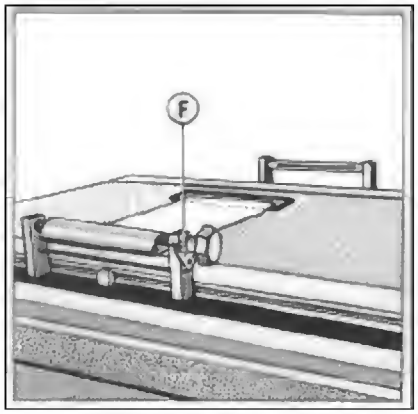


Compression Belt

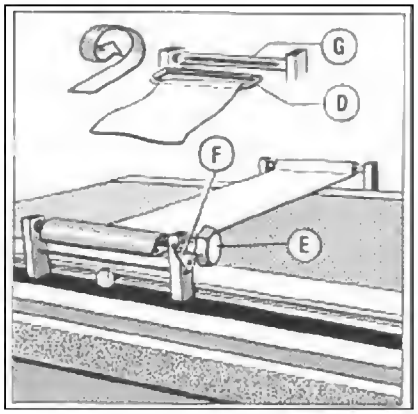
Fastening and application:

Slide support frame **B** into profile rail at wall side or into Bucky profile rail. Turn knob screw to clamp in position.

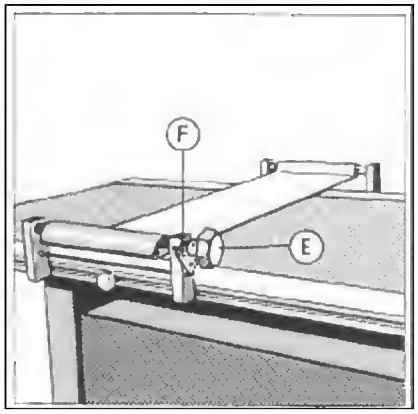
Slide tightener **A** into front profile rail (operator side). Turn hand screw **C** to clamp in working position opposite of **B**



Guide belt through complementary frame and once around frame bar. Fix belt bracket **D** into slot of shaft **G**. Turn ratchet mechanism **E** to tighten belt.



Press ratchet mechanism **F**. Unroll belt and stretch across patient.



Untightening:

Press locking lever **F**

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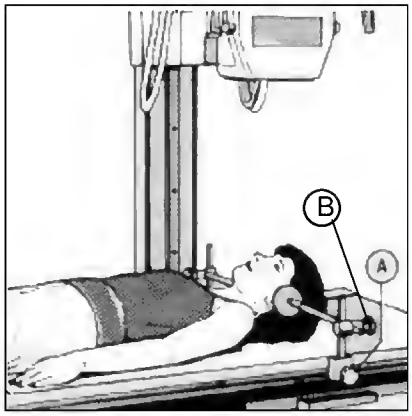
Head Supports / Hip Supports

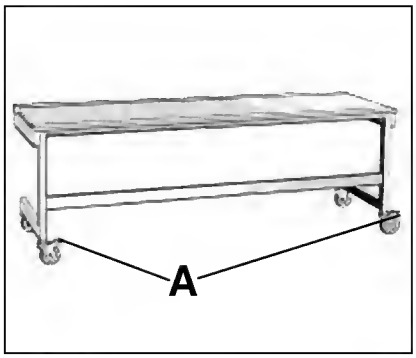


The head supports slide into profile rails of the table or Bucky. The supports can be clamped in any position desired. The patients head is fixed to the appropriate exposure position by cushioned plates on adjustable bars.

Hand screw **A**: Clamping Head Supports to table top or Bucky.

Hand screw **B**: Clamping of head holder

Patient positioning table

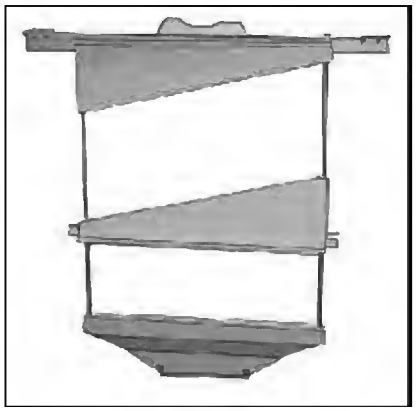


The patient positioning table can be moved easily on steering rolls independent of the equipment and can be arrested in each direction with the two double stop rolls A.

Patient positioning pad for patient positioning table

The patient positioning pad is radiotransparent. Used for comfortable positioning of the patient on the table top.

Cassette holder for hang over



Put in cassette holder for cassettes 13x18 until 35x43 over the front plate of the Bucky in both profile rails.

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Maintenance:

Important note:
Like all technical equipment, this unit requires also a regular maintenance service to increase the safety of the equipment.

Operator's service and maintenance

The operator has to check the x-ray equipment for defects as listed below:
In case of functional defects or other deviations from the normal operation the equipment has to be switched off at once and the service company has to be informed.
The equipment can not be used before all defects have been eliminated.

Daily routine checks

Check indicator light and operating elements for proper functioning.

Weekly checks

Check all cables and their connections for treaces of wear.

Periodic maintenance

For trouble-free operation of the Cosmos-2 as well as safety for patient and user it is necessary to carry out a technical maintenance from the service company every 12 months.

Please see „technical maintenance" of the mounting instruction.
The steel rope of the column has to be replaced every three years.

Attention:
In case of failure from components, which can limit the safety of the equipment, original spare parts have to be used.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of work that was done. Also the certificate should show the date of repair, the name of the service company and the signature of the technician.

Cleaning:

The equipment must be switched off before cleaning. Plastic surface should only be cleaned with mild soap. Do not use strong cleaners or solvents as they will damage the finish or blur the lettering.

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At least once a month external parts and exposed tracks on which rollers move should be wiped to remove foreign material that may have accumulated.
DO NOT USE A DAMP CLOTH.
Wipe the tracks with a cloth lightly soaked with light machine oil or WD-40.

To protect the finish, polish the equipment with PURE liquid paste wax. Do not use wax containing a cleaning substance. Polish all enameled metal surfaces.

Disinfection:

The equipment has to be switched off before disinfection. Only disinfection methods can be used that correspond to the relevant regulations and rules as well as the protection for explosion.
Spray disinfection is not recommended because it can get in the inside of the x-ray equipment.

The Council Directive 93/42/EEC on Medical Devices
Article 12

This document is revised at the moment by the council.

However the Article 12 must be followed by the company or the legal person who put this X-ray unit into work.

The user is responsible for compliance and implementation of national deviations in the EC.

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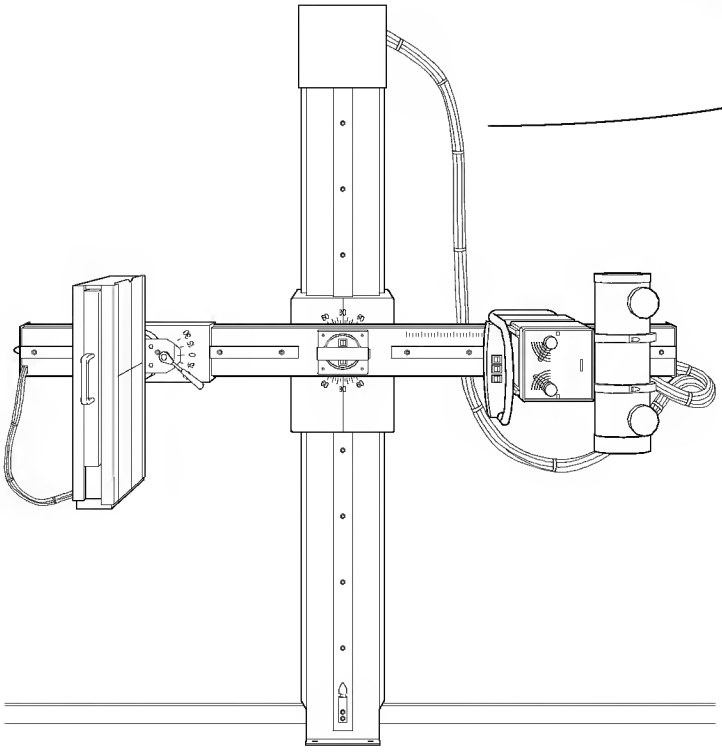
Name Plate Location:

Labeling:



Specifications are subject to change without notice. TV/Ru

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